Proposed Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (CAG-00250R)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes that National Coverage Determination (NCD) Manual sections 40.5 and 100.1 be modified to be consistent with the following conclusions:

The evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP) and laparoscopic adjustable gastric banding (LAGB) are reasonable and necessary for Medicare beneficiaries who are under 65 years of age, have a body-mass index (BMI) $\geq$ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. CMS is seeking comment on this evidence and its implications for coverage, and for the range of patients under age 65 who would be covered. We are particularly interested in comments on the potential to expand coverage for this population under the "Coverage with Evidence Development" (CED) option.

In addition, the evidence is adequate to conclude that approved bariatric surgery procedures for Medicare beneficiaries are reasonable and necessary if the facility performing the procedure meets the following CMS facility standards:

- Each institution will have a credentialing program that ensures that surgeons performing bariatric surgery shall have;
    - appropriate board certification,
    - training and experience that meet approved nationally recognized guidelines, and
    - training and clinical expertise in managing and treating morbidly obese patients prior to the decision to undertake surgery and have experience in managing post-surgery patients for at least one year after surgery.
- Each institution will ensure that individuals who provide services and/or supervise services in the bariatric surgery program are qualified to provide or supervise such services.
- Each institution will have an integrated program for the care of the morbidly obese patient that provides:
    - ancillary services such as specialized nursing care, dietary instruction, counseling, support groups, exercise training, and psychological assistance as needed;
    - a multidisciplinary bariatric surgery team with written descriptions of the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of bariatric surgery, rehabilitation, critical care anesthesia, and nutrition counseling for the morbidly obese and post-bariatric surgery patients.
- Each institution will establish and implement written policies to address and document adverse events that occur during the management of a bariatric surgery patient.
- Each institution will have staff and readily available consultants in cardiology, pulmonology, rehabilitation and psychiatry who have prior experience with bariatric surgery patients.
- Each institution will have a written informed consent process that informs each patient of: 1) the evaluation process; 2) the surgical procedure; 3) alternative treatments; 4) national and center-specific rates for potential surgical risks, hospital lengths of stays, 30-day mortality and other relevant outcome measures; 5) risk factors that could affect the success of the surgery; 6) the patient’s right to refuse the intervention.

- Each institution will have sufficient operating room tables, equipment, instruments and supplies specifically designed or appropriate for bariatric surgery; a recovery room capable of providing critical care to obese patients; an intensive care unit with similar capabilities; equipment with manufacturer's specifications, such as hospital beds, commodes, chairs, wheelchairs, etc., that accommodate the morbidly obese; and radiology and other diagnostic equipment capable of handling morbidly obese patients.

The evidence is not adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP) and laparoscopic adjustable gastric banding (LAGB) are reasonable and necessary for Medicare beneficiaries who are 65 years of age or older; therefore, CMS will non-cover these procedures in this population.

The evidence is not adequate to conclude that the following bariatric surgery procedures are reasonable and necessary and they are therefore non-covered for all Medicare beneficiaries:

a. open vertical banded gastroplasty,
b. laparoscopic vertical banded gastroplasty,
c. open sleeve gastrectomy,
d. laparoscopic sleeve gastrectomy,
e. open adjustable gastric banding,
f. open biliopancreatic diversion with or without duodenal switch, and
g. laparoscopic biliopancreatic diversion with or without duodenal switch.

The two non-coverage determinations in the National Coverage Determination Manual (NCDM) remain unchanged: Gastric Balloon (NCDM Section 100.11) and Intestinal Bypass (NCDM Section 100.8).

CMS is requesting comment on this proposed decision. We are specifically interested in comments on the potential to cover the 65 and older population under CED. Though we have not finalized the CED Guidance Document, we believe this issue does meet the general guidelines outlined in that draft guidance document. CED would also allow the expansion of national coverage to this older population, with some limitations. Adherence to Departmental regulations including the Health Insurance Portability and Accountability Act (HIPAA, Public Law 104-191) and human research protections (45 CFR Part 46) would, as with all CED, be a requirement.

We are also asking for public comment on the facility criteria to include the potential to establish more definitive bariatric surgery volume criteria for facilities and surgeons. In addition, we believe these standards will best be applied by organizations experienced in this process. Therefore, as part of this proposed decision, we are requesting comment on appropriate entities to apply these standards. We are aware that the American College of Surgeons and the American Society of Bariatric Surgeons have developed accrediting programs and we are specifically asking for comments about their level of competence in performing this facility review.

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Proposed Decision Memo

TO: Administrative File: CAG-00250R
Bariatric Surgery in Medicare Beneficiaries - Reconsideration

FROM:

Steve Phurrough MD, MPA
Director, Coverage and Analysis Group

Marcel E Salive, MD, MPH
Director, Division of Medical and Surgical Services

Ross J Brechner, MD, MS(Stat.), MPH
Lead Medical Officer, Division of Medical and Surgical Services

Katherine Tillman, RN, MA
Lead Analyst, Division of Items and Devices

Susan Harrison, MPP
Analyst, Division of Medical and Surgical Services

Deirdre O'Connor, RN, MAS
Analyst, Division of Medical and Surgical Services

SUBJECT: Proposed Coverage Decision Memorandum for Bariatric Surgery for Morbid Obesity

DATE: Wednesday, November 23, 2005

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes that National Coverage Determination (NCD) Manual sections 40.5 and 100.1 be modified to be consistent with the following conclusions:

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II. Background

Epidemiology

Obesity is a growing epidemic in the United States with over 60% of the population classified as overweight or obese.[1] Overweight and obese persons have an increased risk of a number of diseases compared to those with normal weight and waist circumference. Some of the most important and common co-morbidities include hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, respiratory problems, and endometrial, breast, prostate, and colon cancers. Because of the relative lack of success of most weight loss programs, persons with obesity have turned to bariatric surgery at an exponentially increasing rate. Bariatric surgery is the focus of this decision memo.

The National Heart, Lung, and Blood Institute (NHLBI) has classified overweight people into groups based on Body Mass Index (BMI is the body weight in kilograms divided by the body height in meters squared):

Overweight = 25-29.9
Class I obesity = 30.0-34.9
Class II obesity = 35.0-39.9
Class III (Extreme) Obesity $\geq$ 40.0

By these definitions, approximately 27% of the US population is obese and an additional 34% are overweight. Obesity is more common in women and overweight is more common in men. Obesity is especially common in African Americans, Native Americans, Native Hawaiians, and some Hispanic populations.[2] Data for the extent of obesity in the Medicare population indicate that in 1999-2000, 33% of men and 39% of women aged 65-74 were obese as were 20% and 25% respectively over the age of 74.[3]

Surgical Treatment

Extremely obese persons often do not benefit from the non-surgical treatments for weight loss and weight maintenance.[4] The Massachusetts Technology Assessment (TA) reported that weight loss in bariatric surgery studies was of a magnitude greater than weight loss in pharmaceutical or diet studies. It cited a weight loss of 20-40 kg at one or two years in surgical studies versus 2-5 kg in pharmaceutical studies.[5]

Using data from the National In-patient Survey (NIS), Pope reported that the rate of performing bariatric surgery procedures increased from 2.7 to 6.3 per 100,000 adults from 1990 to 1997.[6] During the same time period gastric bypass surgery increased from 54% to 84% of all bariatric surgery in the US.

Several modifications of bariatric surgery have developed over the last several years. Two major types of surgery are now being employed. One diverts food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and adsorption of nutrients cannot occur - a malabsorptive procedure. The other restricts the size of the stomach and decreases intake - a restrictive procedure. Other surgeries combine both types of procedures. Initially, bariatric surgery was developed as an open procedure, but in recent years successful attempts have been made to convert some of the procedures to laparoscopic procedures and new procedures have been developed solely as laparoscopic. The following are descriptions of bariatric surgery procedures:

Roux-en-Y Gastric Bypass (RYGBP) (Open/Lap)

RYGBP achieves weight loss through both gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. The RYGBP procedure has been performed regularly since the early 1980s and was first performed laparoscopically in the early 1990s. RYGBP is one of the most common types of weight loss procedures in current use, with approximately 50,000 cases performed in 2001.

Biliopancreatic Diversion (BPD) with and without Duodenal Switch (DS) (Open/Lap)
BPD, like RYGBP, combines both restrictive and malabsorptive mechanisms. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with the RYGBP. As such, patients eat relatively normal-sized meals and do not need to radically restrict intake, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. Although this procedure is less commonly performed than either banding procedures or RYGBP, the approach is strongly favored by some bariatric surgeons because this procedure appears to yield higher Excess Weight Loss (EWL). The partial biliopancreatic diversion with duodenal switch is a variant of the BPD procedure. Recently, a number of centers in the United States and Canada have begun to perform this procedure, which involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastamosis and a lower ileo-ileal anastamosis.

Sleeve Gastrectomy (Open/Lap)
Sleeve Gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It is often the first step in a two -stage procedure when performing RYGBP.

Laparoscopic Adjustable Gastric Banding (LABG) (Lap)
Gastric banding achieves weight loss by gastric restriction, not malabsorption. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands used today are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. Today, essentially all of the banding procedures are performed laparoscopically. The open version of adjustable gastric banding (AGB) is not performed at present.

Vertical Gastric Banding (VBG) (Lap)
VBG uses mechanical restriction to cause weight loss, a similar mechanism to that used in LAGB, with no malabsorption component. However, the upper part of the stomach is stapled creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less. VBG was one of the more common surgical procedures for weight loss in the late 1980s and early 1990s but has been largely supplanted by LAGB since 1995 and now its role in the treatment of patients with severe obesity is limited. The open version of VBG is no longer performed.

III. History of Medicare Coverage

Current Coverage Policies

NCD Manual Section 40.5 *Obesity*
Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions, or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity are covered when such services are an integral and necessary part of a course of treatment for one of these medical conditions. However, program payment may not be made for treatment of obesity unrelated to such a medical condition since treatment in this context has not been determined to be reasonable and necessary.

NCD Manual Section 100.1 *Gastric Bypass Surgery for Obesity*
Gastric bypass surgery for extreme obesity is covered under the program if (1) it is medically appropriate for the individual to have such surgery; and (2) the surgery is to correct an illness which caused the obesity or was aggravated by the obesity.

NCD Manual Section 100.8 *Intestinal Bypass*
The safety of intestinal bypass surgery for treatment of obesity has not been demonstrated. Severe adverse reactions such as steatorrhea, electrolyte depletion, liver failure, arthralgia, hypoplasia of bone marrow, and avitaminosis have sometimes occurred as a result of this procedure. It does not meet the reasonable and necessary provisions of §1862(a)(1) of the Act and is not a covered Medicare procedure. This procedure is not under consideration in this NCD.

NCD Manual Section 100.11 *Gastric Balloon*
The gastric balloon is a medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety. The use of the gastric balloon is not covered under Medicare, since the long term safety and efficacy of the device in the treatment of obesity has not been established. This procedure is not under consideration in this NCD.

Request for Reconsideration

On May 23, 2005 CMS opened a national coverage determination (NCD) at the request of the American Society for Bariatric Surgery, the American Obesity Association, Ethicon Endo-Surgery Inc. (a Johnson & Johnson company), INAMED Corp., U.S. Surgical, a division of Tyco Healthcare Group LP, and Transneuronix Corp. The requestors asked that Medicare cover the following bariatric surgery procedures:

a. open Roux-en-Y gastric bypass,
b. laparoscopic Roux-en-Y gastric bypass,
c. open adjustable gastric banding,
d. laparoscopic adjustable gastric banding,
e. open biliopancreatic diversion with duodenal switch,
f. laparoscopic biliopancreatic diversion with duodenal switch,
g. open vertical banded gastroplasty,
h. laparoscopic vertical banded gastroplasty,
i. open sleeve gastrectomy,
j. laparoscopic sleeve gastrectomy.

Surgical treatment for obesity, as addressed in sections 40.5 and 100.1 of the NCD manual, will be reviewed in this NCD. Sections 100.8 and 100.11 were not part of the request and, as we are unaware of any new evidence of benefit from these procedures or the use of these procedures currently, we will not review these sections in this proposed decision memorandum.

Benefit Category Determination

Under 1861(s)(I) bariatric surgery is a physician service and as such qualifies as a benefit.

Bariatric surgery, as considered in this proposed decision memorandum, is used for the treatment of co-morbidities and medical complications related to obesity and, therefore, is not considered cosmetic surgery.

IV. Timeline of Recent Activities

From August 1, 2004 to November 11, 2004 CAG prepared an evidence review and summary of evidence for the MCAC.

On November 4, 2004 the Evidence Review and Summary of Evidence was presented at the MCAC on Bariatric Surgery.

On May 23, 2005 CMS accepted a formal request for reconsideration of the existing policy on gastric bypass and initiated review.

On June 24, 2005 initial comments posted to the tracking sheet available electronically at: http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=160.

V. FDA Status

Surgical procedures are not subject to FDA approval. However, LapBands™ are utilized in some bariatric surgery and the date and content of FDA approval for this device can be found at http://www.fda.gov/cdrh/mda/docs/p000008.pdf

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of reasonable and necessary. The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Coverage Advisory Committee, evidence-based guidelines, professional society position statements, expert opinion, and public comments.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical questions relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve net health outcomes for patients. A detailed account of the methodological principles of study design the agency staff utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix 1.

VII. Evidence

Introduction

In order to appraise the benefits of bariatric surgery for obese patients in comparison with non-surgical medical management, CMS chose the following outcomes:

- sustained weight loss,
- short-and-long-term mortality,
- complications of surgery (also using length of stay as a marker), and
- effect on co-morbidities.

The acceptable studies concentrated on these outcomes and our review of the evidence demonstrated these outcomes to be most important when evaluating the effectiveness and impact of bariatric surgery procedures. We also looked for these outcomes in both patients with co-morbidities and without co-morbidities.

We assessed health benefits of bariatric surgery via a review of the literature and through input from the Medical Coverage Advisory Committee (MCAC) that met on November 4, 2004.

Discussion of Evidence Reviewed

1. Questions

Is the evidence sufficient to conclude that the following bariatric surgery procedures will improve net health outcomes for Medicare patients:

a. open Roux-en-Y gastric bypass,
b. laparoscopic Roux-en-Y gastric bypass,
c. open adjustable gastric banding,
d. laparoscopic adjustable gastric banding,
e. open biliopancreatic diversion with duodenal switch,
f. laparoscopic biliopancreatic diversion with duodenal switch,
g. open vertical banded gastroplasty,
h. laparoscopic vertical banded gastroplasty,
i. open sleeve gastrectomy, and
j. laparoscopic sleeve gastrectomy.

The evidence reviewed includes external technology assessments, a CMS internal technology assessment of new or reconsidered evidence, as well as professional society position statements and expert opinion.

2. External Technology Assessments

“Clinical Guidelines On The Identification, Evaluation, And Treatment Of Overweight And Obesity In Adults: The Evidence Report.” 1998. National Heart Lung and Blood Institute (NHLBI).

The NHLBI report examined articles from January 1980 through September 1997 regarding gastric bypass, gastroplasty with diet, VBG, horizontal-banded gastroplasty (HBG), BPD, and RYGBP. According to the report, co-morbid conditions improved after VBG and RYGBP. Complications following surgery, however, were frequent and substantial and included readmission, depression, staple line failure, dilated pouch, and dehydration/malnutrition. If less invasive weight loss treatments fail in patients at high risk for obesity-related morbidity or mortality, NHLBI recommended bariatric surgery as an option for carefully selected patients with a BMI >40 or >35 with co-morbidities. There was no discussion of the effects of bariatric surgery of those 65 years of age or older.

“Pharmacological and Surgical Treatment of Obesity.” Southern California Evidence-Based Practice Center. RAND Corporation. July 2004: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Rand reviewed articles dating from 1966 to 2003 regarding gastric banding, VBG and other gastroplasty, jejunoileal bypass, RYGBP, and BPD. The report found that surgery controls obesity-related co-morbid conditions more effectively than non-surgical treatments. No clear differences in mortality or complications exist between different surgical procedures. Overall mortality for bariatric surgery remained between 1 and 2%. No recommendations were made beyond future research priorities. There was limited discussion on bariatric surgery and this assessment did not address bariatric surgery in people 65 years or older.

“Newer Techniques in Bariatric Surgery for Morbid Obesity.” The Technology Evaluation Center (TEC) of the Blue Cross and Blue Shield Association. September, 2003.

The Blue Cross Blue Shield TEC examined articles from January 1985 through August 2003 regarding open and laparoscopic gastric banding, BPD, and long-limb gastric bypass. Due to insufficient data, the committee remained unable to confidently evaluate the safety and net health benefit of any of the bariatric surgeries except RYGBP. The TA calculated mortality associated with RYGBP as being between 0.5 and 0.6%. No recommendations were made beyond the acceptance of Roux-en Y as the sole procedure meeting BCBS TEC criteria for coverage. The mean age for study participants did not exceed 50.

“Executive Report.” August 4, 2004. Commonwealth of Massachusetts Betsy Lehman Center for Patient Safety and Medical Error Reduction. Expert Panel on Weight Loss Surgery.

The Massachusetts expert panel reviewed articles published between January 1980 and February 2004 regarding RYGBP, VBG , gastric banding, and BPD. The report maintained that laparoscopic and open RYGBP improve or resolve many co-morbid conditions but benefits of LAGB remain unclear. RYGBP risks were reported to be substantial and include pulmonary embolism, intestinal leak, wound infection, staple line failure and long-term nutritional deficiencies. Laparoscopic techniques had a steeper learning curve than other equivalent open procedures. LAGB risks included band and port related problems, GERD, and esophagitis. The LAGB revision rate may have been as high as 10%. LAGB mortality (< 0.5%) was found lower than RYGBP or BPD. The expert panel provided extensive and specific recommendations regarding bariatric surgeons and bariatric surgery programs. There was no discussion of bariatric surgery in the elderly.

“Diagnosis and Treatment of Obesity in the Elderly”. University of Pittsburgh. December 18, 2003: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

AHRQ reviewed articles published between January 1980 and February 2003 regarding gastric bypass, LAGB, VBG and DS. According to this assessment, current data were insufficient to evaluate safety or efficacy of bariatric surgery in the elderly. In young obese patients, surgery was shown to improve diabetes, hypertension, dyslipidemia and quality of life (QOL), but higher age increased the perioperative risk of bariatric surgery. The report stated that surgical data was poor and adverse events had the capacity to be very serious, including death. No recommendations were made beyond future research suggestions to analyze effects of surgery in elderly.

“Bariatric Surgery for Obesity”. ECRI September 2004: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

ECRI reviewed articles regarding bariatric surgery in persons aged $\geq$ 18 years, published in 1994 or later having either a randomized controlled trial (RTC) or a before/after comparison with morbid obesity and having sample size of $\geq$ 10. Concentration was on outcome of QOL and co-morbidity reduction. ECRI found strong evidence that bariatric surgery reduced short-term mortality, labeling it in the range of 0.1 - 1.5%, while data on other outcomes was rated as weak to moderate. This assessment did a separate evaluation of evidence for bariatric surgery in obesity in adolescents (less than 21 years old). This was the only age related assessment of evidence.

“Laparoscopic Bariatric Surgery for Morbid Obesity”. ECRI May 2005: for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

ECRI reviewed articles regarding a comparison of Laparoscopic to open bariatric surgery published through 1/2005, including studies having an RTC or meta-analysis. The TA concluded that there was not enough evidence to answer the question of outcome differences between open and laparoscopic for the modalities studied. The evidence was not evaluated by age.

3. Internal Technology Assessment

Literature Search
CMS performed a search of the literature using the following terms: Bariatric OR Obesity AND Surgery AND Elderly OR Older. The limitations used were human, English, publication date from 04/04/03 to 09/01/05. The database searched was Medline.

Scientific Articles
Each person on a team of four graded all 213 papers located by our search as either unacceptable or acceptable. Fifty-two papers referenced the elderly and 43 of those papers were published earlier than April 2003. Of all 213 papers, 27 were considered acceptable. Only data from acceptable papers were utilized in our Summary of Evidence. Of special note was that many of the studies reported to date had not had population samples representative of the general severely overweight population with respect to race, ethnicity, cultural or socioeconomic background, gender or age. Also, of note was the paucity of randomized control trials (RCTs), non-randomized control trials (NRCTs), and good quality data for the over age 65 population. Evidence tables for the literature reviewed are in Appendix 2.

Outcomes
Sustained Weight Loss
Five of 27 acceptable articles contained data on sustained weight loss and 1 of 27 articles had data on sustained weight loss in persons over the age of 65. Of the 7 TAs, none had sustained weight loss data on persons over age 65 and 5 of 7 had data on sustained weight loss. We did not find data comparing sustained weight loss in persons having bariatric surgery and at least one pre-op co-morbidity with those having bariatric surgery and no pre-operative co-morbidities.

The Swedish Obese Subjects (SOS) study, a case-control study with respect to outcomes from bariatric surgery,[7] reported statistically significant long-term weight loss after different types of bariatric surgery (banding and gastric bypass) as compared to controls (non-surgical management). The study matched subjects at baseline on 18 variables, including gender, age, height, and weight. At eight years of follow-up, among 251 surgically treated patients, the average weight loss was 20 kg (or 16 percent of body weight) as compared to no change in the control group of 232 medically treated patients. Weight loss in the operated group ranged from 4.4-35kg. The SOS study, the only carefully controlled trial with long-term results, also demonstrated that there was approximately 8-9 kg more sustained weight loss in gastric bypass as compared to VBG. Their results provided strong evidence of the superiority of surgical treatment for the patients that were enrolled (37-57 year olds with an average BMI of about 41kg/m2).

The NHLBI TA reported that bariatric surgery (gastric restriction [vertical gastric banding] or gastric bypass [Roux-en Y]) could result in substantial weight loss, and therefore is an available weight loss option for well-informed and motivated patients with a BMI $\geq$ 40 or $\geq$ 35 with co-morbid conditions and acceptable operative risks. They also added that RYGBP produced greater long-term weight loss than gastric partitioning alone or VBG and was substantially safer than jejunoileal bypass. The Massachusetts TA reported that open and laparoscopic RYGBP produced short-term weight loss and improvements in co-morbid medical conditions. Dolan reported that BPD with or without DS was effective in producing weight loss. LAGB produced variable short-term weight loss and improvements in obesity-related co-morbidities and had higher average mortality rates than RYGBP or malabsorptive procedures In a case-control study by Dolan et al., it was determined that weight loss was higher in BPD than in LAGB, 64% excess weight loss (EWL) vs. 48%EWL at 24 months.[8] In a study by Shen, LAGB was compared to RYGBP and it was pointed out that in LAGB, if patients had more than 6 visits postoperatively, they had 8% more EWL (50% vs. 42%), whereas there was no difference in the RYGBP group.[9] Chau, in a study of LAGB, reported that after adjusting for demographics, older patients and patients with pre-existing diabetes mellitus or COPD had greater odds of above average %EWL after bariatric surgery, whereas being female, having a higher BMI, and having hypertension were risk factors for a lower %EWL result.[10] Suter, in a prospective randomized study comparing LAGB to the Swedish Adjustable Gastric Band (SAGB), reported that evaluation of short and midterm results of these two modalities showed an equivalent %EWL.[11]

The one acceptable paper that we found with sustained weight loss in persons close to age 65 was authored by Sugerman (2004). He reported on a cohort of 80 patients over age 60 with an average age of 63 years. His paper reported that, at 5 years after bypass surgery, there was an average of 27% weight loss, and 50% EWL.[12] Finally, in the Gonzalez study of bypass surgery for obesity in persons over age 50, weight loss plateaued at 18 months with EWL averaging 68%, similar to that in younger age groups.[13]

Short-term mortality

In our CMS overall review, 8 of 27 acceptable papers and 4 TAs reported data on short-term mortality results, two of which pertained partially to persons over 65. We were unable to locate any data comparing short-term mortality in persons having bariatric surgery and at least one preoperative co-morbidity, with those having bariatric surgery and no preoperative co-morbidities. The Buchwald article reported the rates of short-term mortality to be 0.1% for purely restrictive procedures, 0.5 % for gastric bypass, and 1.1% for BPD or DS.[14] Flum reported a short-term mortality rate in Medicaid bariatric surgery (gastric bypass) patients of 1.9% and that 81% of the short-term mortality cases were associated with surgeon inexperience. Inexperienced bariatric surgeons, defined in this study as a bariatric surgeon who had performed less than 20 operations, performed nineteen percent of all surgical cases in that study.[15] Data from that paper yielded approximately 6.0% short-term mortality rate in the hands of inexperienced surgeons, while the rate for experienced bariatric surgeons was 0.5%. In another paper analyzing compete Medicare claims data from 1997 to 2002, Flum reported that the short-term mortality rate in persons over age 65 was 4.8% as compared to 1.7% for those under age 65. This paper also found a reduction in all-cause mortality directly associated with surgeon experience.[16] Livingston recently reported a rate of 3.2% in persons over 65 as compared to 1% for those under age 65.[17] In Herron's review, short-term mortality relating to gastric banding and gastric bypass was in the range of 0.0-1.0%, while in BPD or DS, it was higher at 0.5%-2.5%.[18] In the Pope study of the National In-hospital Survey (NIS) in-hospital mortality for all bariatric surgery was reported to be 0.37% from 1990 to 1997. In the Massachusetts TA, LAGB had a short term mortality rate of < 0.5%. The overall VBG range of short-term mortality was 0-1.4%[14, 19]and for all of bariatric surgery, short-term mortality ranged from 0.1% to 2.0%.[14,18,19]

In two cohort studies by Fernandez, risk factors for peri-operative death in open or laparoscopic gastric bypass were postoperative leak, pulmonary embolus, higher pre-operative weight, and hypertension. Other risk factors for mortality were age, male gender, having diabetes, and having had a specific surgical procedure with RYGBP having a 2.7% short -term mortality rate, open RYGBP a 1.5% short-term mortality rate and LRYGBP a 0.5% rate. There were no deaths in persons older than 60 (number of cases over age 60 not shown in paper) despite the fact that being a higher age was predictive of a higher chance of mortality.[20,21] Livingston found that male gender is a predictor of mortality for patients undergoing gastric bypass surgery.[22]

Longevity
With respect to longevity, 4 of 27 of our acceptable articles had data on longevity and 2 of 27 had longevity data on persons over the age of 65. Of the 7 TAs we reviewed, none had any data on longevity. We were unable to locate any data comparing longevity in persons having bariatric surgery and at least one pre-operative co-morbidity, with those having bariatric surgery and no pre-operative co-morbidities.

There was some evidence that bariatric surgery patients had prolonged longevity and less Years of Life Lost (YLL). Black males aged 30, with a BMI of 40, had 8YLL as compared to 5YLL for white males aged 30 with the same BMI. White females aged 30, with BMI of 40 had roughly the same YLL as white males (4-5). These differences almost disappeared for persons aged 60 and above with a BMI of 40, with black females actually having negative years of life lost at higher ages.[23] Flum reported an increase in longevity in those post-bariatric surgery Medicaid patients given that they survived to year one after the surgery.

Co-morbidities
Nine of 27 of our acceptable articles had data on co-morbidities; however, none had co-morbidity data on persons over the age of 65. Of the 7 TAs we reviewed, none had co-morbidity data on persons over age 65 and 4 of 7 had data on co-morbidities in the general population.

Regarding the prevalence of co-morbidities in the population eligible for bariatric surgery, Pope demonstrated that the percentage of persons that had obesity surgery and had at least one major pre-operative co-morbidity was estimated to be 20.8% in 1990 and 31.4% in 1997. Yet in Gonzalez' cohort study, for persons 50 years old or older, 47 of 52 (90%) had co-morbidities such as degenerative joint disease 60%, diabetes and gastroesophageal reflux disease (GERD) 40%, and hypertension 56%. Approximately 90% of each type improved post-operatively with the exception of hypertension where 56% improved. In a study by Residori, 57% of patients had at least one metabolic complication with 30% having diabetes, 38% dyslipidemia, and 38% hypertension.[24] Approximately one-third of the diabetes cases and one-half of the dyslipidemia and hypertension cases were previously undiagnosed. Dindo calculated, after adjustment for BMI and age, that the occurrence of dyslipidemia was higher in Caucasians than Hispanics or African Americans, while hypertension rates were about the same.[25]

In the Swedish Obesity Study (SOS), ten-year follow-up of 1006 post-bariatric surgery patients aged 37 to 57 years showed that the two-year incidence rates of diabetes, hypertension, and low high density lipoprotein (HDL) were statistically significantly higher in the control group (diabetes 16% vs. 0.5%, hypertension 23% vs. 6.0%, and elevated HDLs 16% vs. 5.0%). From the SOS, Sjostrom/ reported that the post-op prevalence of hypertension, after 8 years follow-up, showed no difference between VBG cases and controls, while there was a statistically significant lowering of hypertension in the group that had GBP as compared to the control group. One important study, the Adelaide Study (Dixon-1988), showed that medical co-morbidities ether improved (47%) or resolved (43%) in all but 4 cases (9% of patients had unsatisfactory weight loss). They reported that 60 percent of the patients who initially had any obesity-related co-morbidity were free of medication for those co-morbidities 3 years after surgery. Buchwald reported that for all types of bariatric surgery, diabetes completely resolved in 77% of cases, and improved or resolved in 86%; hypertension completely resolved in 62% and improved or resolved in 78%; hyperlipidemia improved in 70%; and obstructive sleep apnea (OSA) was resolved in 85%. In Dolan's case-control study the resolution of co-morbidities was similar across groups having BPD as compared to those having LAGB, ranging from 66% in hypertension to 100% of OSA.

Complications
In our CMS review, 6 of 27 acceptable papers and 4 of 7 TAs reported data on complications in patients, while 2 of 27 acceptable papers and no TAs reported data on persons over 65 years. We were unable to locate any data comparing complication rates in persons who had bariatric surgery and at least one pre-op co-morbidity, with those having bariatric surgery and no pre-op co-morbidities.

In a study by Shikora, involving a series of 750 consecutive patients undergoing LRYGBP at a high volume academic center, the complication rate was reduced by more than 50% when comparing the first 100 cases against the next 650 in the program regardless of performing surgeon experience.[26]

The Massachusetts TA reported that laparoscopic adjustable silicone gastric banding (LAGB) had a lower complication rate than the other bariatric surgery procedures. The Dolan study showed that LapBPD had a markedly higher rate of complication (56%) as compared to 6.3% in LAGB. Heron's review underscored the difference in rates of complications from RYGBP and BPD versus VBG. For example, bypass procedures had lower re-operation rates and LAGB had lower wound infection rates. In that study, the LAGB complications were somewhat lower than those in either RYGBP, BPD, or VBG and a known complication of LRYGBP was conversion from LRYGBP to the open procedure during surgery. A study by Felix showed that 3% of laparoscopic procedures were converted to open, while other studies showed a range of 1.6% re-operations in RYGBP, 11.3% in VBG, and 7.7 to 10% in LAGB.[27] In the converted group, risk factors for conversion were higher age, higher weight, and male gender.

In other types of complications, Fernandez identified risk factors for having a leak as male gender, having diabetes, and RYGBP; both LRYGBP and open RYGBP. In general, the NHLBI reported that wound infections ranged from 2.3% in laparoscopic cases to 11.4% in open cases. In the Livingston study on procedure and in-hospital complication rates using NHIS data, risk factors for complications were higher age, and being male. In that study, the most frequent complication was pneumonia (at 2.6%), while the short-term mortality rate was 0.4%. Over the 1990 to 1997 period, Pope found significant decreases of in-hospital re-operations for bleeding, abscess, or dehiscence (2.2% to 1.4%); respiratory complications (7.4% to 5.9%); and a trend toward decreased in-hospital complications. The Rand TA reported reduced occurrence of wound and incisional hernia complications in patients treated laparoscopically, compared to open procedures. Malnutrition occurred in 2.5% in VBG to 16.9% in RYGBP and 5.8% for all bariatric surgery.[1,2] Notable in another Livingston study was that male gender was a predictor of morbidity for patients undergoing gastric bypass surgery.[28]

4. Medicare Coverage Advisory Committee (MCAC) - (See Questions in Appendix 3)

At the MCAC meeting on bariatric surgery held on November 4, 2004, a number of questions were presented to the committee for consideration. CMS created a Summary of evidence for the MCAC and it is available at Summary of Evidence. A summary of the MCAC recommendations is presented below.

- With regards to bariatric surgery in persons with one or more co-morbidities, the MCAC indicated that the evidence presented addressed the effectiveness of bariatric surgery in the treatment of obesity in patients with one or more co-morbidities compared to non-surgical medical management. The committee members were confident regarding the validity of the scientific data presented on weight loss and felt confident that bariatric surgery would very likely result in sustained weight loss as compared to non-surgical management.

- With respect to the outcomes of short-term mortality, long-term mortality, and co-morbidities, the committee was moderately confident in the validity of the scientific data presented, and believed that bariatric surgery would positively affect these outcomes when compared to non-surgical management.

- Regarding the different types of bariatric surgery in obese persons with one or more co-morbidities, the committee had a generally moderate to high confidence in the ability of all the modalities considered (RYGBP, BPD, and Banding) to yield a net health benefit. RYGBP drew the most support.

- With regards to bariatric surgery in persons with no co-morbidities, data was insufficient to answer any of the questions presented.

- Lastly, based on the scientific evidence presented, the MCAC believed, with moderate confidence, that even though the evidence in the over 65 population was sparse, the results of bariatric surgery in obese patients with one or more co-morbidities could be generalized to the older Medicare population.

5. Guidelines

Evidence Based - After vigorous search on the terms “Bariatric Surgery”, “guidelines” AND “evidence-based”, CMS was unable to locate true evidence-based guidelines for bariatric surgery. There were consensus-based guidelines. For example, a search of the National Guideline Clearinghouse website yielded “Guidelines for the Clinical Application of Laparascopic Surgery” published by Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) based on expert consensus.

Certification/recertification - The American College of Surgeons, the American Society of Bariatric Surgeons and SAGES have published criteria for certification and recertification. These criteria can be found at the following urls:
http://www.obesity-online.com/guidelines_ASBS.htm
http://www.lapsurgery.com/BARIATRIC%20SURGERY/SAGES.htm
http://www.lapsurgery.com/BARIATRIC%20SURGERY/ACS.htm

6. Professional Society Statements

CMS received comments from three professional societies.

The American College of Surgeons (ACS) commented that the evidence is adequate to evaluate the following bariatric surgery procedures: open and laparoscopic Roux-en-Y gastric bypass, adjustable gastric banding, biliopancreatic diversion with duodenal switch and vertical banded gastroplasty. ACS does not feel it is necessary for CMS to define a list of co-morbid conditions to qualify patients for bariatric surgery. ACS urges CMS to limit coverage to those facilities and surgeons meeting specific standards. They suggest that the standards they have established for their Bariatric Surgery Center Network are appropriate for all patients. In addition, ACS recognizes the limited data available on outcomes of bariatric surgery on the elderly and supports the need for continuous monitoring and evaluation of the surgical care for the morbidly obese. ACS has developed a Bariatric Surgery Module under its National Surgical Quality Improvement Program (NSQIP) registry and is prepared to modify it to collect any additional data. ACS does note that preoperative psychiatric evaluation and pre- and postoperative nutritional counseling are essential parts of any successful bariatric surgery program. Finally, ACS recommends that CMS cover bariatric surgery limited to programs with the necessary resources and standards and offers the College's Bariatric Surgery Center Network to serve as a basis for identifying and approving qualified programs.

The North American Association for the Study of Obesity (NAASO) offered that surgery is appropriately placed in the continuum of obesity treatments. NAASO feels that the evidence is adequate to support the safety and effectiveness of the surgical options included in the requested NCD. They agreed with listing the currently known co-morbid conditions related to obesity with the understanding that the list continues to expand as research continues to expand knowledge on this issue. Concern was expressed that obese patients should not be denied access to care because the condition is not included on the list. NAASO supported the inclusion of criteria for surgeons and facilities and suggested the use of the criteria used by the surgical societies. Finally, NASSO supported the need for the collection of data especially in the elderly population. However, they expressed concern about making sure the data collection process did not become so burdensome that it might reduce the number of participating providers. They suggested collaboration with physicians on the data collection process. NASSO also encouraged the inclusion of coverage for perioperative care to ensure the best outcomes.

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) strongly endorsed coverage of Bariatric surgery. They stated that “It will be critical to identify centers with good outcome data and to use that to channel patients for care to ensure the best value for our healthcare dollars”.

7. Expert Opinion

None received

8. Public Comments

Initial Public Comments

After initiating the NCD process, the tracking sheet was posted marking the initial 30 day public comment period which began May 24, 2005. CMS utilizes the initial public comments to inform its proposed decision. We will respond in detail to the final public comments on this proposed decision.

In addition to general concerns, CMS requested public comment on the following issues.

1. Is the evidence adequate for evaluating health outcomes of the bariatric surgery procedures listed in the request?
2. Should CMS define the list of co-morbid conditions that qualify a patient for bariatric surgery?
3. Should CMS adopt criteria for facilities or surgeons who deliver these procedures?

4. Is there a need for routine data collection on the delivery or outcomes of bariatric surgery?

CMS received one hundred and sixty nine public comments; seventy-eight percent are positive comments in support of providing coverage for bariatric surgery for obesity and twenty-two percent are negative and opposed to coverage by Medicare of bariatric surgery. The comments that specifically addressed the four issues posted on the tracking sheet are summarized separately.

The general comments in support of coverage of bariatric surgery are numerous and varied. There are a number of comments that declared that obesity is a disease not a choice. A common theme throughout many of the positive comments is that many of the co-morbid conditions associated with obesity (e.g., diabetes, hypertension, sleep apnea, reflux disease, high cholesterol, debilitating joint pain, and many others) are either greatly relieved or even eliminated after successful weight loss surgery. There are cost benefit references that state that the cost of treating the co-morbid conditions that plague the morbidly obese are greater than the cost of the surgery. There is also reference to the fact that people who successfully undergo this surgery are able to get off of disability and return to work. One commenter feels that “Cost and clinical data unequivocally supports coverage for weight loss surgery.” Another commenter stated “Co-morbidities of obesity are costly and bring suffering and enormous expense to all involved. WLS [weight loss surgery] is the only research proven, successful treatment for weight loss.”

There are a number of comments stating that weight loss surgery is the only effective means for weight loss for the morbidly obese. There are a large number of testimonials in support of coverage from people who have had weight loss surgery and health care professionals who have been involved in the care of these patients. There are many references to the improved quality of life that this surgery offers.

There are suggestions about also including coverage for mini-gastric bypass procedure as well as long term follow up care. Some comments reflect that this is a great tool for preventive medicine. (This procedure is statutorily prohibited as a preventive measure.)

The Blue Cross and Blue Shield Association (BCBSA) comments that in June of 2005 the Technology Assessment Center (TEC) Medical Advisory Panel (MAP) reaffirmed a previous assessment that available evidence for laparoscopic adjustable banding, biliopancreatic diversion, and long-limb gastric bypass was not sufficient to form conclusions on the benefits and risks compared to open gastric bypass. BCBSA further states that the MAP will review the reassessment of laparoscopic gastric bypass at its fall, 2005, meeting. The MAP also expresses concerns about the number of bariatric surgery procedures performed outside of multidisciplinary programs. BCBSA feels that studies are needed to compare outcomes for bariatric surgery to those of non-surgical alternatives. Further, BCBSA lists in their comments the draft programmatic requirements for bariatric centers of excellence. Finally, BCBSA cites the need for a national registry to promote quality improvement which will require funding, management, and oversight. More specific comments from BCBSA to each of the posted questions are incorporated into to summary for each question.

Several of the negative comments suggest that there is a prejudice and bias toward the obese and that providing coverage supports that bias. A number of the commenters cite recent information from the CDC and other sources that contradicts the impression that obesity and premature mortality are linked. There are a number of comments referencing that the support of this surgery is influenced by the potential profit that can be made and that organizations other than the surgeons and companies that financially benefit should be consulted prior to any coverage decision.

The feeling that life style interventions and non-surgical services such as nutritional counseling, physical therapy and non-weight bearing exercise are a better alternative is identified. Providing subsidized nutritious foods and safe places to exercise is also suggested. Many express thoughts that surgery is a bad idea. Some consider this surgery an amputation and mutilation of major organs of the body which can not be a good thing.

Twenty-one negative comments cite that this is a dangerous surgery with one comment calling it “a dangerous procedure with horrific side effects”. The feeling that this surgery is still experimental in terms of whether it achieves long term health improvements and objections to spending Medicare funds is expressed in a number of the comments. Some also refer to problems of weight loss in people over 60 and that it might increase the risk of serious illness in this age group. There is also reference to the fact that the weight loss after surgery is not sustained and much of the weight is regained.

Comments specific to each of the four questions that were posted are summarized as follows.

Question 1. Is the evidence adequate for evaluating health outcomes of the Bariatric surgery procedures listed in the request? Of the 169 comments, we received twenty comments that specifically addressed this question. Of the twenty comments, twelve commenters suggest that there is not adequate evidence for evaluating health outcomes of the bariatric surgery procedures listed in the request. Seven commenters specifically note an absence of long-term data and studies on bariatric surgery. One commenter suggests that the rate of complications for bariatric surgery is unacceptable. Of the twenty comments, ten commenters suggest that there is adequate evidence for evaluating health outcomes of the bariatric surgery procedures listed in the request. Commenters note improved outcomes and fewer co-morbidities as evidence that bariatric surgery is an effective treatment.

Question 2. Should CMS define the list of co-morbid conditions that qualify a patient for Bariatric surgery? Of the 169 comments, we received eight comments that specifically addressed this question. Seven commenters suggest that CMS should define a list of co-morbid conditions that qualify a patient for bariatric surgery. One commenter suggests that CMS should not create a list of co-morbid conditions that would qualify a patient for bariatric surgery because over time science could reveal more obesity related conditions that would not be on the list of conditions.

Question 3. Should CMS adopt criteria for facilities or surgeons who deliver these procedures? Twenty comments posted to the web site in some way reference the adoption of criteria for facilities or surgeons who are involved in these procedures. All are generally supportive of the development of criteria/guidelines; however some commenters feel that CMS should not be developing the criteria/guidelines. There are a number of suggestions to use the qualifications set up by the bariatric surgery specialists specifically mentioning the American Society of Bariatric Surgery. Some of the comments reference Centers of Excellence as providing safe and effective provider and facility choices because they have rigorous standards and verified results.

Question 4. Is there a need for routine data collection on the delivery or outcomes of bariatric surgery? Seven comments posted to the web site reference the need for data collection. Generally, these comments are supportive of the need for collecting data. It is suggested that this should be a condition of coverage with a public-private collaboration to establish a national registry. Some feel this would promote quality improvement and provide information on the optimal procedure for the different types of patients. One commenter expresses concern because the Medicare population makes up a very small percentage of the focus population and this might cause a redirection of resources that should be aimed at the non-Medicare population. The question was presented, “If CMS allows coverage and links it to collection of evidence, how will CMS target such research and what clinical questions will CMS seek to answer?” This commenter feels that “CMS should refrain from applying coverage with evidence development (CED) until its guidance document has been finalized and the appropriate application of CED is defined through the public comment process.” Additionally, concern is expressed about CMS creating policy that will limit access for patients who need such important treatment.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1862(l)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” § 1862(a)(1)(A) of the Act.

Medical treatment for obesity includes dietary manipulation, behavior modification and medication. These therapies have been tried individually and in combination, but with only limited long-term success. However, based on the lower risk-benefit ratio for medical treatment, we believe it should be routinely attempted and shown to be unsuccessful before considering a patient for bariatric surgery. There are no consistent standards in the literature regarding length of a medical treatment trial and, therefore, we are unable to specify a specific time interval. A number of trials and guidelines recommend 6 to 12 months and we believe that to be reasonable.

In our review we found, in the general population, that post-surgical sustained weight loss may be an attainable goal with combination or malabsorptive procedures showing greater weight loss than restrictive procedures, which, in turn, demonstrate significantly more weight loss than no surgery. The NCD requestors recommended that bariatric surgery procedures be covered for beneficiaries with a BMI $\geq$ 35% with at least one co-morbidity or with a BMI $\geq$ 40% without any co-morbidity. In general, for outcomes of short-and long-term mortality, improvement in co-morbidities, sustained weight loss and complications of surgery, we found there is little or no data enabling comparisons of persons who had at least one pre-operative co-morbidity with those who had none. We did find supporting evidence that sustained and sufficient weight loss may improve or resolve co-morbid conditions. Buchwald et al., in their JAMA metanalysis, reported that overall, bariatric surgery resulted in a 61.2% (58.1 -64.4) EWL. They also reported that, as a result of that EWL, co-morbidities such as diabetes, hyperlipidemia, obstructive sleep apnea and hypertension improved or resolved in a majority of patients. The data are consistent with the conclusion that health benefits of surgery are limited to those persons with one or more co-morbidities related to obesity. Therefore, we believe that bariatric surgery should be reserved for that group.

With respect to Medicare beneficiaries under the age of 65 years, we found that there was sufficient evidence to support open and laparoscopic RYGBP and LAGB as reasonable and necessary for selected patients in this younger population. For these two modalities, sustained weight loss was well documented (ranging from an approximate mean of 50% EWL in RYGBP to approximately 30-50% in LAGB) and short-and-long-term mortality were low (<2%).[1,4,14,5,7] However, we found that data supporting open vertical banded gastroplasty, laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, laparoscopic sleeve gastrectomy, open adjustable gastric banding and open and laparoscopic biliopancreatic diversion with or without duodenal switch are generally sparse and not adequate to draw conclusions in this population. Thus, we non-covered these procedures; i.e., they are not reasonable and necessary in this group of beneficiaries. We will review any additional data submitted during the public comment period to determine possible revision of this noncoverage.

With respect to the Medicare population age 65 years and older, we were unable to find adequate data that either demonstrated a net health benefit of bariatric surgery in this population or enabled generalization of data for younger persons to this population. The one TA addressing the older Medicare population was also unable to locate sufficient data. Though the MCAC recommended, with a moderate level of confidence, that the results from trials in younger populations could be generalized to the population $\geq$65 years of age, subsequently published data on the higher surgical risks in this population demonstrated a higher surgical risk than the data available to the MCAC, with one exception. The overall surgical risk in persons over 65 years of age is higher than that in the younger population. Flum reports mortality rates in the 65 and older population to be 2.8 times higher at 30 days, 3 times higher at 90 days and 2.85 times higher at one year, when compared to the population under age 65. Surgeons in the highest quartile of bariatric surgery procedure volumes had similar rates of early mortality in both age groups (1.8 % 90 day mortality in patients less than 65 years and 1.1 % mortality in patients greater than 65 years). Since there are no clinical trial data in the older population and the surgical risk is significantly higher we believe that it is inappropriate to perform this surgery in this population and thus do not believe that, with the data available that any bariatric surgery procedure is reasonable and necessary for the Medicare population age 65 and older.

CAG commonly reviews published data that include patients younger than 65. In those cases if we determine a benefit in that younger population, we then evaluate the potential of generalizing this data to the 65 or over Medicare population. We look at a number of factors and include biologic and pathophysiologic as well as adverse outcome data. For bariatric surgery in the older age group, the higher surgical risk makes generalization of data on bariatric surgery to that population difficult. Thus, we are proposing noncoverage of this population. CMS has developed a concept known as "Coverage with Evidence Development (CED)". (See http://www.cms.hhs.gov/coverage/guidance.asp.) Some commenters recommended that option for this decision. We are requesting public comment on the potential to revise this noncoverage and apply this CED concept through clinical trials and/or prospective cohort studies comparing surgery with non-surgical management for the age 65 and older population and to potentially broaden coverage of the under 65 population. Adherence to Departmental regulations including the Health Insurance Portability and Accountability Act (HIPAA, Public Law 104-191) and human research protections (45 CFR Part 46) would, as with all CED, be a requirement.

We also found that while short-term mortality is low, experienced surgeons performing bariatric surgery have a lower rate of short-term mortality than inexperienced surgeons. Flum also found an indication that longevity was decreased in persons with high BMI, and increased in persons having bariatric surgery if they survived to one-year post surgery. In the younger age group, in addition to the limitations above, we are also concerned with the significant variation in outcomes among surgeons. Higher short-term mortality is also of particular concern in the elder population. Both Flum and Livingston have demonstrated the increased mortality in the older population undergoing bariatric surgery and Flum has demonstrated the marked variability in outcomes based on surgical experience.[16,17] This increased risk has led the American College of Surgery and the American Society of Bariatric Surgeons to develop criteria for facilities performing this surgery. They, along with numerous other commenters, strongly support CMS limiting coverage of these procedures to centers of excellence. In addition to surgeon qualifications, the Societies and the commenters list other facility criteria crucial to good outcomes. We have integrated these comments into our proposed standards. Thus, we have determined that bariatric surgery procedures are reasonable and necessary only if performed in facilities that have demonstrated competence in managing patients preoperatively, perioperatively and postoperatively. Therefore, for all Medicare beneficiaries undergoing RYGBP or LAGB, these procedures must be performed in facilities that have met the following facility standards:

- Each institution will have a credentialing program that ensures that surgeons performing bariatric surgery shall have;
    - appropriate board certification,
    - training and experience that meet approved nationally recognized guidelines, and
    - training and clinical expertise in managing and treating morbidly obese patients prior to the decision to undertake surgery and have experience in managing post-surgery patients for at least one year after surgery.
- Each institution will ensure that individuals who provide services and/or supervise services in the bariatric surgery program are qualified to provide or supervise such services.
- Each institution will have an integrated program for the care of the morbidly obese patient that provides:
    - ancillary services such as specialized nursing care, dietary instruction, counseling, support groups, exercise training, and psychological assistance as needed;
    - a multidisciplinary bariatric surgery team with written descriptions of the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of bariatric surgery, rehabilitation, critical care anesthesia, and nutrition counseling for the morbidly obese and post-bariatric surgery patients.
- Each institution will establish and implement written policies to address and document adverse events that occur during the management of a bariatric surgery patient.
- Each institution will have staff and readily available consultants in cardiology, pulmonology, rehabilitation and psychiatry who have prior experience with bariatric surgery patients.
- Each institution will have a written informed consent process that informs each patient of: 1) the evaluation process; 2) the surgical procedure; 3) alternative treatments; 4) national and center-specific rates for potential surgical risks, hospital lengths of stays, 30-day mortality and other relevant outcome measures; 5) risk factors that could affect the success of the surgery; 6) the patient's right to refuse the intervention.

- Each institution will have sufficient operating room tables, equipment, instruments and supplies specifically designed or appropriate for bariatric surgery; a recovery room capable of providing critical care to obese patients; an intensive care unit with similar capabilities; equipment with manufacturer's specifications, such as hospital beds, commodes, chairs, wheelchairs, etc., that accommodate the morbidly obese; and radiology and other diagnostic equipment capable of handling morbidly obese patients.

We are asking for public comment on these criteria to include the potential to establish more definitive bariatric surgery volume criteria for facilities and surgeons.

We believe these standards will best be applied by organizations experienced in this process. Therefore, as part of this proposed decision, we are requesting comment on appropriate entities to apply these standards. We are aware that the American College of Surgeons and the American Society of Bariatric Surgeons have developed accrediting programs and we are specifically asking for comments about their level of competence in performing this facility review.

IX. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes that National Coverage Determinations (NCD) Manual sections 40.5 and 100.1 be modified to be consistent with the following conclusions:

The evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP) and laparoscopic adjustable gastric banding (LAGB) are reasonable and necessary for Medicare beneficiaries who are under 65 years of age, have a body-mass index (BMI) $\geq$ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. CMS is seeking comment on this evidence and its implications for coverage, and for the range of patients under age 65 who would be covered. We are particularly interested in comments on the potential to expand coverage for this population under the “Coverage with Evidence Development” (CED) option.

In addition, the evidence is adequate to conclude that approved bariatric surgery procedures for Medicare beneficiaries are reasonable and necessary if the facility performing the procedure meets the following CMS facility standards:

- Each institution will have a credentialing program that ensures that surgeons performing bariatric surgery shall have;
    - appropriate board certification,
    - training and experience that meet approved nationally recognized guidelines, and
    - training and clinical expertise in managing and treating morbidly obese patients prior to the decision to undertake surgery and have experience in managing post-surgery patients for at least one year after surgery.
- Each institution will ensure that individuals who provide services and/or supervise services in the bariatric surgery program are qualified to provide or supervise such services.

- Each institution will have an integrated program for the care of the morbidly obese patient that provides:
    - ancillary services such as specialized nursing care, dietary instruction, counseling, support groups, exercise training, and psychological assistance as needed;
    - a multidisciplinary bariatric surgery team with written descriptions of the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of bariatric surgery, rehabilitation, critical care anesthesia, and nutrition counseling for the morbidly obese and post-bariatric surgery patients.
- Each institution will establish and implement written policies to address and document adverse events that occur during the management of a bariatric surgery patient.
- Each institution will have staff and readily available consultants in cardiology, pulmonology, rehabilitation and psychiatry who have prior experience with bariatric surgery patients.
- Each institution will have a written informed consent process that informs each patient of: 1) the evaluation process; 2) the surgical procedure; 3) alternative treatments; 4) national and center-specific rates for potential surgical risks, hospital lengths of stays, 30-day mortality and other relevant outcome measures; 5) risk factors that could affect the success of the surgery; 6) the patient's right to refuse the intervention.
- Each institution will have sufficient operating room tables, equipment, instruments and supplies specifically designed or appropriate for bariatric surgery; a recovery room capable of providing critical care to obese patients; an intensive care unit with similar capabilities; equipment with manufacturer's specifications, such as hospital beds, commodes, chairs, wheelchairs, etc., that accommodate the morbidly obese; and radiology and other diagnostic equipment capable of handling morbidly obese patients.

The evidence is not adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP) and laparoscopic adjustable gastric banding (LAGB) are reasonable and necessary for Medicare beneficiaries who are 65 years of age or older; therefore, CMS will non-cover these procedures in this population.

The evidence is not adequate to conclude that the following bariatric surgery procedures are reasonable and necessary and they are therefore non-covered for all Medicare beneficiaries:

a. open vertical banded gastroplasty,
b. laparoscopic vertical banded gastroplasty,
c. open sleeve gastrectomy,
d. laparoscopic sleeve gastrectomy,
e. open adjustable gastric banding,
f. open biliopancreatic diversion with or without duodenal switch, and
g. laparoscopic biliopancreatic diversion with or without duodenal switch.

The two non-coverage determinations in the National Coverage Determination Manual (NCDM) remain unchanged: Gastric Balloon (NCDM Section 100.11) and Intestinal Bypass (NCDM Section 100.8).

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